JUN 2 7 2000

K001157

Alcon

ALCON Research, Ltd.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134
(817) 293-0450

April 7, 2000

510(K) SUMMARY

Submitted by:

Sherri J. Lakota
Manager, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134
(817) 568-6179 (Phone)
(817) 551-4630 (Fax)

Trade Name:	MONARCH®[1] II IOL Delivery System
Common Name:	IOL Delivery System
Classification Name:	Intraocular Lens Guide, 21 CFR 886.4300

[1] MONARCH® is a registered trademark of Alcon Laboratories, Inc.

1. Predicate Device

The predicate device to which we are claiming equivalence is:

a. MONARCH IOL Delivery System, (Alcon Laboratories, Inc.)

2. Device Description

The MONARCH II IOL Delivery System consists of two parts: an autoclavable, reusable titanium handpiece and a sterile, single-use cartridge. It is a device used for folding and delivering ACRYSOF®[2] intraocular lenses into the eye for replacement of the human crystalline lens. The system provides a controlled means to reliably place the ACRYSOF intraocular lens into the capsular bag.

3. Intended Use of the Device

The intended use of this device is to fold and deliver Alcon ACRYSOF intraocular lenses into the eye for replacement of the human crystalline lens.

4. Summary of the Technological Characteristics of the Device

The MONARCH II IOL Delivery System utilizes a sterile, single use cartridge and a reusable handpiece to deliver ACRYSOF lenses. The cartridge with enhanced lubricity is designed for easy loading and reliable folding of ACRYSOF lenses. The handpiece accepts the cartridge and delivers the lens by using a plunger to express the lens. The plunger head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by a screw mechanism to ensure a smooth and well controlled lens delivery.

5. Summary of the Performance Data

The performance test demonstrated that the MONARCH II IOL Delivery System can be used to deliver ACRYSOF IOLs without adversely affecting the overall shape, power, resolution, or cosmetic attributes of the lenses. The test lenses were delivered smoothly and unfolded completely in a controlled fashion.

6. Conclusions

The MONARCH II IOL Delivery System is easy to use, properly delivers the Alcon ACRYSOF intraocular lens, and is substantially equivalent to the Alcon MONARCH IOL Delivery System.

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[2] ACRYSOF® is a registered trademark of Alcon Laboratories, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2000

Ms. Sherri J. Lakota
Alcon Research, LTD.
6201 South Freeway
Fort Worth, TX 761342-2099

Re: K001157
Trade Name: MONARCH II IOL DELIVERY SYSTEM, MODEL C3, CARTRIDGE SIZE B
Regulatory Class: I
Product Code: 86 KYB
Dated: June 21, 2000
Received: June 22, 2000

Dear Ms. Lakota:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indication for Use

510(k) Number (if known): K001157

Device Name: MONARCH® II IOL Delivery System

Indications For Use:

The intended use of this device is to fold and deliver Alcon ACRYSOF® intraocular lenses into the eye for replacement of the human crystalline lens.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lawrence Yannuzzi

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001157

(Optional Format 3-10-98).